



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. | |
|-----------------------|-------------|----------------------|---------------------|------------------|--|
| 10/535,504 | 05/18/2005 | Ira Sanders | SAND3.0-003PCT/US | 9381 | |
| 47375 | 7590 | 02/04/2009 | EXAMINER | | |
| OMRI M. BEHR | | SWARTZ, RODNEY P | | | |
| 325 PIERSON AVENUE | | ART UNIT | | PAPER NUMBER | |
| EDISON, NJ 08837-3123 | | 1645 | | | |
| | | MAIL DATE | | DELIVERY MODE | |
| | | 02/04/2009 | | PAPER | |

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

| | | | |
|------------------------------|-------------------------|---------------------|--|
| Office Action Summary | Application No. | Applicant(s) | |
| | 10/535,504 | SANDERS, IRA | |
| | Examiner | Art Unit | |
| | Rodney P. Swartz, Ph.D. | 1645 | |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1) Responsive to communication(s) filed on 09 December 2008.
 2a) This action is **FINAL**. 2b) This action is non-final.
 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4) Claim(s) 1-20 and 25 is/are pending in the application.
 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
 5) Claim(s) _____ is/are allowed.
 6) Claim(s) 1-20 and 25 is/are rejected.
 7) Claim(s) _____ is/are objected to.
 8) Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9) The specification is objected to by the Examiner.
 10) The drawing(s) filed on _____ is/are: a) accepted or b) objected to by the Examiner.
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 a) All b) Some * c) None of:
 1. Certified copies of the priority documents have been received.
 2. Certified copies of the priority documents have been received in Application No. _____.
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

| | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ . |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____. | 6) <input type="checkbox"/> Other: _____ . |

DETAILED ACTION

1. **THE FINALITY OF THE LAST OFFICE ACTION IS HEREBY VACATED.**
2. Applicant's Response to Final Office Action, received 9 December 2008, is acknowledged. Claims 3, 4, 5, 9, 12, 14 and 15 have been amended. New claim 25 has been added.

The examiner notes that the amendment of claim 17 is not accurate. The deleted word should be "administered", not "administered". However, to expedite prosecution, the examiner is permitting the correction in spelling and the amended form of claim 17 is entered.

The examiner notes that concerning the addition of claim 25 applicant has not indicated support for the claim in the specification. However, to expedite prosecution, the examiner is permitting the addition of claim 25 because of support for the claim in the specification, page 24, lines 10-14.

3. Claims 1-20 and 25 are pending and under consideration.

Rejections Withdrawn

4. The objection to claim 17 is withdrawn in light of the claim amendment.
5. The rejection of claim 4 under 35 U.S.C. 112, second paragraph, as being indefinite for "derived", is withdrawn in light of the claim amendment.

Claim Rejections - 35 USC § 102

6. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

7. Claims 1-3, 8, 11-13, 15 and 16 are rejected under 35 U.S.C. 102(b) as being anticipated by Sanders et al (WO95/28171, 26 October 1995).

The claims are drawn to a method of blocking or reducing physiological reaction in a mammal to the interaction of IgE antibodies present in said mammal upon contact with the corresponding antigen, by administration to said mammal of a therapeutically effective amount of a neurotoxin (CnT) isolated or purified from *Clostridia* sp. The physiological reaction is manifested by a condition or symptoms selected from a group consisting of allergic rhinitis, infectious rhinitis, serous otitis media, sinusitis, pulmonary disease, nasal congestion, food allergies, allergic dermatitis, sneezing, coughing, itching, excess mucous secretion related to allergic reactions, bronchitis, emphysema and hyperactive asthma. The CnT may be administered by injection, myringotomy, injection into the pterygopalatine space through the palate, or passage through the nasal wall to the sphenopalatine ganglia.

Since the scope of the claims is drawn to a method of blocking or reducing physiological reactions and not to actual blocking of IgE antibodies binding with antigen, Sanders et al teach the claimed methods in that the reference teaches controlling at least one symptom of rhinorrhea, otitis media, excessive salivation, asthma, COPD, excessive stomach acid secretion, spastic colitis or excessive sweating in mammals, including humans. The methods may be performed by topical application of botulinum toxin onto the nasal mucosa or injection into the sphenopalatine ganglion and by the utilization of nasal sprays or drops of the seven known types of botulinum toxin, i.e., A-G as well as the closely related toxins produced by *Clostridium butyricum* and *Clostridium beratti* (Abstract; page 4, lines 2-35; Example V; Example VII; Example VIII; claims 1, 4, 6, 7, 8, 12, 13, 18-21).

Claim Rejections - 35 USC § 112

8. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

9. Claims 4-7, 9, 10, 14, 17-20 and 25 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The claims are dependent from rejected claims.

Conclusion

10. No claims are allowed.

11. Any inquiry concerning this communication or earlier communications from the Examiner should be directed to Rodney P. Swartz, Ph.D., Art Unit 1645, whose telephone number is (571) 272-0865. The examiner can normally be reached on Monday through Wednesday from 9:00 AM to 7:30 PM EST. Thursday is the examiner's work at home day.

If attempts to reach the Examiner by telephone are unsuccessful, please contact the Examiner's Supervisor, Robert B. Mondesi (571)272-0956.

The fax phone number for the organization where this application or proceeding is assigned is (571) 273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/Rodney P. Swartz, Ph.D./

Primary Examiner, Art Unit 1645

January 30, 2009